

137



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,106	09/28/2000	Randal K. Buddington	2343-104-27	8636

7590 02/27/2006

Patent Prosecution Services
Piper Marbury Rudnick & Wolfe LLP
1200 Nineteenth Street, N.W.
Washington, DC 20036-2412

EXAMINER

OH, SIMON J

ART UNIT PAPER NUMBER

1618

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,106

Applicant(s)

BUDDINGTON ET AL.

Examiner

Simon J. Oh

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20,23,24,27,30,31,33,34,37 and 41-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20,23,24,27,30,31,33,34,37 and 41-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, all received on 22 November 2005.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 20, 27, and 37 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is hereby withdrawn in view of the present amendment to these claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 18-20, 23, 24, 27, 30, 31, 33, 34, 37, and 41-46 under 35 U.S.C. 103(a) over Paul *et al.* and Van Loo *et al.* is maintained.

Claims 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Paul *et al.* and Van Loo *et al.*

The Paul *et al.* patent teaches an orally administered composition for promoting gastrointestinal health comprised of an effective amount of dietary fiber (See Abstract; and

Art Unit: 1618

Column 3, Lines 39-57). The dietary fiber is a member selected from the group consisting of fructo-oligosaccharides, such as inulin, pectins, pectic polysaccharides, and mannans such as guar gum (See Column 4, Lines 1-10). The Paul *et al.* patent further states that the disclosed compositions can be used for treating conditions facilitated by infections caused by pathogenic microorganisms such as *E. coli*, Salmonella, and Candida (See Column 16, Lines 21-26).

The Paul *et al.* patent does not make mention of the degree of polymerization of a dietary fiber.

The Van Loo *et al.* patent teaches a fructan-containing composition with an average degree of polymerization of 15 or higher (See Column 4, Lines 22-28; and Claim 1). The Van Loo *et al.* patent also discloses chicory inulin with an average degree of polymerization of about 25 (See Claim 18). The daily doses effective in providing prevention and treatment of colon cancer range from 0.01 to 2 g/kg of body weight (See Column 5, Lines 51-54).

One of ordinary skill in the art would be motivated to combine the two prior art references as they both broadly show that the administration of dietary fiber, such as inulin, is beneficial for the gastrointestinal health of a subject in need thereof. As the compositions in both prior art references have similar various effects which are known in the art to be beneficial to a subject, one of ordinary skill in the art would have a reasonable chance of success in combining the two references. Such effects include a reduction of intestinal transit time, a decrease of the intestinal pH, a bifidus stimulating activity in the colon, bulking of the stool, increase in stool frequency, and an improvement in lipid metabolism (See Paul *et al.*, Columns 2, 3, and 7-11; and Van Loo *et al.*, Column 2). Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 22 November 2005 have been fully considered but they are not persuasive.

The current amendments to the claims do not sufficiently clarify the patentability of the applicant's instantly claimed invention. Although the applicant has taken great efforts to clearly define the bounds of the scope of the instantly claimed invention, the examiner cannot ignore what is nevertheless the broad scope embodied in the instant claims. The applicant has substantially closed the scope of the composition to be administered in the instantly claimed methods, as embodied by the phrases, "composition consisting of" and composition consisting essentially of". However, the scope of the overall method itself remains broad, as embodied by the phrase "method for the treatment . . . comprising".

The examiner must consider this broad scope in determining patentability of the claims. In the view of the examiner, the broad scope of the overall instantly claimed methods allow for the inclusion of additional elements that are not specifically recited in the instant claims. As such, it is the position of the examiner that the prior art applied in the rejections of record are proper.

Furthermore, in determining what has been disclosed by the prior art and how it reads on the scope of the instantly claimed invention, it is the position of the examiner that the physiological co-extensiveness of the gastrointestinal system, as disclosed by the prior art, and the blood stream (i.e., the circulatory system) as recited in the instant claims allow for the prior art references to be properly applied against the instantly claimed invention. As such, the pending claims will remain rejected.

Correspondence

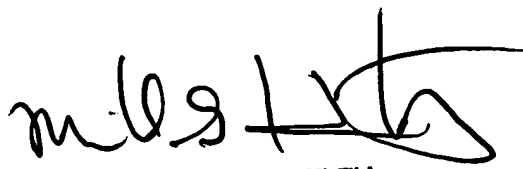
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sj0



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER